HFI-35 D1116B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
1141 Central Parkway
Cincinnati, OH 45202

January 21, 1997

WARNING LETTER
CIN-97-177

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Paul Rothermel
184 SR 44
Hartville, Ohio 44632

Dear Mr. Rothermel:

Investigations of your cattle dealer business located at 184 State Route 44 in Hartville, Ohio conducted by the U.S. Food & Drug Administration and Ohio Department of Agriculture in December 1996 confirmed that you sold bob veal calves for slaughter as food in violation of sections 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

On or about March 4, 1996 you bought calves at the [redacted] sales barn. On March 5, 1996 you offered several calves at the [redacted]. The calves bore no back tag numbers when delivered to [redacted] They were assigned back tags at the receiving dock. The calf identified with back tag #31DA 3247 was bought by [redacted] and subsequently sold to [redacted] of [redacted] and shipped to [redacted] in [redacted] where it was slaughtered for [redacted] The calf contained 0.99 parts per million (ppm) tetracycline in the kidney when tested by the USDA Laboratory. The limit for this drug in edible tissue is set by regulation at 0.25 ppm. The illegal level of drug residue caused this calf to be adulterated food when it was purchased for slaughter.

On or about May 20, 1996 you bought calves at the [redacted] sales barn. On May 21, 1996 you offered several calves at th[redacted] The calves bore no back tag numbers when delivered to [redacted] They were assigned back tags at the receiving dock. The calf identified with back tag #31DA 7268 was bought by [redacted] and subsequently sold to [redacted] of [redacted] and shipped to [redacted] in [redacted] where it was slaughtered for [redacted] The calf contained 01.74 ppm of Neomycin in the kidney when tested by the USDA Laboratory. The limit for this drug in edible tissues is set by regulations at 0.25 ppm. The illegal level of drug residue caused this calf to be adulterated food when purchased for slaughter.

The investigation confirmed that you purchased these animals without any assurance they were drug residue legal and thusly caused them to be introduced into interstate commerce for slaughter. These animals with excessive levels of drug residues are adulterated food, when intended for slaughter, and are prohibited by Section 301(a) of the FD&C Act from being introduced or delivered for introduction into interstate commerce.

The above is not intended as an all inclusive list of violations. A review of your file at Cincinnati District Office of FDA reveals several other instances over the past five (5) years where you have sold animals with illegal drug residue levels which were slaughtered for human food. As a buyer and shipper of animals for slaughter you are responsible for assuring that you do not ship or cause to be shipped adulterated food across state lines, that is, medicated animals which are intended for slaughter. It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the FD&C Act. If you buy a medicated animal for slaughter for human food and the animal is shipped interstate you can be held responsible. If the medicated animal had already been shipped interstate and you buy it and cause it to be slaughtered you can be held responsible. If you sell a medicated animal for slaughter within the state and that slaughterhouse ships interstate you can be held responsible.

You must assure yourself the animals you purchase for slaughter are drug residue legal. Further, it means you cannot buy animals for which you cannot obtain a drug residue legal assurance and then sell them in a manner wherein they are diverted to slaughter. You can be held responsible for any animal slaughtered for human food which you caused to be sold, enters interstate commerce and if it is found to contain illegal levels of drug residues.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action, such as injunction, without further notice.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made.

Your reply should be sent to the Food and Drug Administration, Cincinnati District Office, Attention: Leonard J. Farr, Compliance Officer, 1141 Central Parkway, Cincinnati, Ohio, 45202.

Sincerely yours,

John R. Marzilli
District Director
Cincinnati District

LJF/clc